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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,999	10/01/2003	Thomas Q. Dinh	PA1289 CIP	7261

7590 08/30/2005

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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TWS

Office Action Summary	Application No.	Applicant(s)	
	10/676,999	DINH ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11 and 26-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/05,11/04,10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, species A, claims 1-10 and 12-25 in the reply filed on 08/15/2005 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 9, 10, 12-16 and 18-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Shanley et al (USPGpub 2002/0082680). Shanley et al discloses a stent (fig. 1) for delivering drugs (title) to a vessel in a body comprising: a stent framework including a plurality of reservoirs (24) formed therein fully capable of having been made by a femtosecond laser ([0068]); a drug polymer positioned in the reservoirs (36 in figs. 7-8); and a polymer layer positioned on the drug polymer (38 and/or 39 in figs. 7-8).

With regard to claims 2 and 3, nitinol, stainless steel as well as other materials are disclosed through out the specification.

With regard to claim 4, the reservoirs comprise micropores (24).

With regard to claim 9, wherein the micropores extend through the stent framework (as seen in figs. 4-19) having an opening on an interior surface of the stent and an opening on an exterior surface of the stent.

With regard to claims 10 and 18-19, cap layer is disclosed (see figs. 7 and 8).

With regard to claims 12 and 13, therapeutic compound such as antisense agent are disclosed ([0069]).

With regard to claims 14 and 15, see figure 11 and [0085] and [0086].

With regard to claims 16 and 20, the polymer matrix is inherently a biocompatible polymer.

With regard to claims 21 and 22, an adhesion layer (84) is positioned between the stent framework and the drug polymer. Any material for layer (84) would inherently be an adhesion promoter since the other material (82) need to adhere to it as well as adhere to the stent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley et al in view of Holloway et al. (US PGpub 20030114917). Shanley et al discloses a stent as discussed above. However, Shanley et al does not discloses the pores having diameter in the range of about 20 microns or less. Holloway et al. teaches another stent for delivering drugs including pores having diameter in the range of about 20 microns or less (1-400, [0013]) for the purpose of holding the drugs. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the pores as taught by Holloway et al. on the stent of Shanley et

al in order to hold drugs since such a modification amounts to mere substitution of one pore size for another in the art of stent for delivering drugs.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley et al in view of Vallana et al (US 6699281). Shanley et al discloses a stent as discussed above. However, Shanley et al does not discloses the pores having diameter in the range of about 20 microns to about 50 microns or depth in the range of about 10 to about 50 microns. Vallana et al teaches another stent for delivering drugs including pores having diameter in the range of about 20 microns to about 50 microns (40, Example 2) or depth in the range of about 10 to about 50 microns (60 which is about 50, Example 2) for the purpose of holding the drugs. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the pores as taught by Vallana et al on the stent of Shanley et al in order to hold drugs since such a modification amounts to mere substitution of one pore size for another in the art of stent for delivering drugs.

Claims 17 and 23-25 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shanley et al. Shanley et al discloses a stent as discussed above.

With regard to claim 17, although Shanley et al discloses the use of alternating layers of phase release drug polymers ([0086]) and discloses anti-proliferative drug, anti-inflammatory drug, and an antisense drug ([0069], [0086]), Shanley et al remains silent as to the specific use of the three drugs in combination in discrete layers. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made when armed with the discloser of "the ability to release different beneficial agents at different points in time" and a

list of such agents (including anti-proliferative drug, anti-inflammatory drug, and an antisense drug) to make the stent of Shanley et al release any of the different beneficial agents from the list at different points in time and would amount to mere design choice. A number of the many combinations possible would including the combination in discrete layers agents of an anti-inflammatory drug, an anti-proliferative drug, and an antisense drug.

With regard to claims 23-25, although Shanley et al discloses stents being self-expanding or mechanically expanded and discloses the use of a balloon and a sheath with a stent and it is inherent that these devices would be used in combination with a device which could be termed a catheter, Shanley et al remains silent as to the specific use of either a balloon catheter or a catheter and sheath for delivering the disclosed stent. It is well known in the art of stent delivery to use either a balloon catheter, a catheter and sheath or both for delivering a stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use either a balloon catheter, a catheter and sheath or both in order to deploying the stent of Shanley et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Solovay (US 5,769,884), and 6,758,859 (US Dang et al).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs

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